



WHI HRT *Update*

2001

New Hormone Program Information

Since our last update to you, the Data and Safety Monitoring Board (DSMB) has finished another review of all the data from the beginning of the study up to February 28, 2001. The DSMB looked carefully at the safety of women in the study and the value of the study to all women across the nation. They unanimously said we should continue the study, because the overall balance between benefits and risks of hormone replacement therapy (HRT) is not clear.

Study Findings as of February 28, 2001

In the spring of last year, we told you that there was “a small increase in the number of heart attacks, strokes, and blood clots in the lungs of women receiving active hormone replacement therapy compared to women taking inactive (placebo) pills. Fewer than 1% of WHI women had any one of these problems, regardless of the type of study pills they were taking. Over time these differences between women on active and placebo pills seem to be getting smaller and may disappear.” The DSMB has now reviewed the data through February 28, 2001 and has told us that there are still more heart attacks, strokes, and blood clots in women taking active hormones. We do not know how this might change in future years.

The Balance Between Benefits and Risks

In trying to understand the overall balance of benefits and risks, the DSMB reviews data on many health conditions, including:

- Heart attacks, strokes, and blood clots

- Hip fractures
- Breast cancer
- Cancer of the colon and rectum
- Cancer of the lining of the uterus (endometrium)
- Memory problems
- Death
- And many other health conditions

Past hormone studies suggested decreased risk of fractures, colon and rectum cancer, memory problems, death, and heart attacks. Some studies also reported possible increased risks for blood clots and breast and uterine cancer. We told you about possible hormone risks and benefits when you joined WHI and in later “HRT Updates”. The WHI Hormone Program is still strongly needed because we do not have clear data about hormone effects on most of these health conditions. Just as WHI had unexpected data about heart attacks, strokes, and blood clots, there is also new information to be gained about other health conditions. At this halfway point in the study, the DSMB could not conclude that hormones provide either an overall benefit or an overall risk to women like you. By continuing the study, we hope that the answer to this will become clear.

What We Are Doing to Understand These Risks?

We have checked to see if the heart attacks, strokes, and blood clots in women on active hormones may be related to any individual

risk factor (for example, age or other health conditions like high blood pressure). So far, we have not found any particular group of women to be at higher risk. Now we are doing laboratory studies using stored blood samples from WHI women to see if we can identify women at risk. Whether or not these laboratory studies give us new information, the DSMB will continue to monitor the progress of the study and the effects of hormones on your health in future years.

The Health of Women in WHI

As a group, women who joined WHI were healthier than average. As a result, the number of heart attacks, strokes, and blood clots in the WHI women is lower than in the general population of U.S. women. Each year in the study, less than one half of one percent of women had a heart attack. The same is true for strokes and blood clots. Even so, more women taking active hormones than women taking placebos developed these conditions.

How You Can Help Maintain your Health

To help prevent heart attacks or strokes, a healthy lifestyle is important, including:

- a healthy diet
- regular exercise
- not smoking
- controlling your weight

Your doctor can help you with risk factors like high blood pressure, high blood cholesterol, and diabetes. If you have had a heart attack or stroke, a healthy lifestyle is even more important. Your doctor may also recommend medications to prevent complications or future problems.

To help prevent blood clots, it is important to:

- control your weight
- exercise your feet and legs if standing still or sitting for a long time

- wear loose-fitting clothes that do not constrict blood flow

Remember to keep exercising your legs and feet if you must stay in bed for any reason. You may want to ask your clinic practitioner for the “WHI Update” on blood clots.

What Can You Do Now?

The most important thing you can do is to stay informed. Please read this information carefully and discuss with our staff any concerns that you have.

There are many more questions about hormones at this time than there are answers. Female hormones are the number one selling prescription drugs in the U.S.—and the world. According to a recent survey by the American Heart Association, 54% of women believe that hormones prevent heart attacks. However, we still do not know if taking hormones for many years prevents heart attacks and improves health. This study is even more important since we told you of the unexpected findings last year. The whole world is waiting for the final results of the WHI. Thank you for your contribution to this study.

Our commitment to you remains. We ask for your continued participation in this effort because we expect WHI to provide answers for women like you and for generations of women to come. As always, your participation is voluntary. We will continue to provide you with new information when it becomes available. And we will do our part to conduct this study according to the highest standards of medical research, so that the results will be as clear and as useful as possible.

